

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**Claim Rejections – Anticipation**

*US Patent No. 5,879,677*

Applicants traverse the rejection under 35 USC 102(b) over US Patent No. 5,879,677 (“del Zoppo”) for the following reasons. In the Office Action, dated September 19, 2005, the Examiner stated that “administration of any of the anticipatory antibodies of del Zoppo et al. in such an amount to have a therapeutic effect is anticipatory to the instant method claims, regardless of the diseases recited in the preambles of the instant claims.” Applicants urge that it is improper to ignore the recitations of the preambles of the present claims. Each claim is directed to a method of administration to the particular diseases in patients “in need thereof.”

Analyzing a method of treatment claim by giving consideration to the particular disease of the patient being treated has been upheld by the Federal Circuit. See *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001), a copy of which is attached hereto. The following passage from *Rapoport* at page 1059, analyzing a claim that began “A method for treatment of sleep apneas comprising . . .”, is illustrative.

First, we note that the disputed phrase “treatment of sleep apneas” is technically part of the preamble of the interference count, because it appears before the transition word “comprising.” However, there is no dispute in this case that the phrase should be treated as a claim limitation. Moreover, without treating the phrase “treatment of sleep apneas” as a claim limitation, the phrase “to a patient in need of such treatment” would not have a proper antecedent basis.

Therefore, a proper claim analysis of a method of treatment claim must take into account the type of patient being treated.

The del Zoppo reference relates to treating “tissue factor mediated reperfusion damage.” See Abstract. “‘Reperfusion’ refers to the process whereby blood flow in the blood vessels is resumed after constriction or obstruction of flow, as in ischemia. Reperfusion may

result following a naturally occurring episode, such as a stroke, or during a surgical procedure where blood flow in vessels is purposely blocked off.” Column 3, lines 29-34. The working example of del Zoppo uses a baboon animal model of occlusion and reperfusion. Column 17, lines 24-25. “All of the animals lacked evidence of disease.” Column 17, lines 14-16.

Because all of the baboons of del Zoppo lacked evidence of disease, del Zoppo cannot anticipate any of the present independent claims. That is, the animal models of del Zoppo were free of any disease and only suffered as a result of injury; del Zoppo relates to treatment of tissue injury following vascular perfusion. The tissue injury following vascular perfusion is a phenomenon present in a short time and is distinct from the diseases of the pending claims.

All of the independent claims relate to diseases occurring over a longer time frame than the animal models of del Zoppo that “all . . . lacked evidence of disease.” Independent claim 9 relates to treatment of a disease having a persistent hypercoagulable state, which is distinct from the short term injury of del Zoppo. Independent claim 27 relates to the treatment of venous thrombosis, which a longer term disease and not mentioned by del Zoppo. Independent claim 36 relates to the treatment of arterial thrombosis, which is a longer term disease and not mentioned by del Zoppo. Independent claim 45 relates to treatment of the diseases resulting from the medical thickening of a vessel, which is a longer term disease and not mentioned by del Zoppo. Therefore, del Zoppo does not anticipate the present invention.

*Randolph et al. (Blood, 1998)*

For the same reasons given above, applicants traverse the rejection under 35 USC 102(b) over Randolph et al. (Blood, 1998). Namely the present invention relates to methods for therapeutic treatment of specific diseases or states, and the recitations of these target diseases in the claims are not taught or suggested by Randolph. Instead Randolph relates to basic research carried out in an *in vitro* model “to investigate how mononuclear phagocytes traverse endothelium in the basal-to-apical direction.” See Abstract. Because Randolph did not disclose administration to patients, much less suggest the therapeutic uses of the present

claims, Randolph cannot anticipate the present invention. Therefore, the rejection over Randolph is improper and should be withdrawn.

*US Patent No. 6,677,436*

As explained below, US Patent No. 6,677,436 does not qualify as prior art because the '436 patent issued on January 13, 2004, which is after the October 10, 1999 earliest priority date of the present application, and is eligible for the safe harbor provision of 35 USC § 103(c), which is reproduced below.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

MPEP §§ 706(l)(1)-(3) discuss in detail how Examiners are to handle the safe harbor provision of this section.

Therefore, in accordance with 35 USC 103(c) and MPEP §§ 706(l)(1)-(3), the undersigned attorney of record states that, the present application and US Patent No. 6,677,436 were, at the time the invention of the present application was made, owned by Chugai Seiyaku Kabushiki Kaisha. In accordance with MPEP § 706.02(l)(2), this statement is sufficient to disqualify US Patent No. 6,677,436 from being used as prior art in a rejection for obviousness against the present claims.

Accordingly, applicants respectfully request the withdrawal of the present prior art rejections.

**Conclusion**

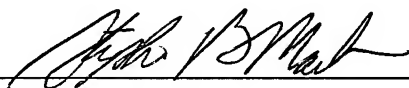
Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date January 19, 2006

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1 of 1 DOCUMENT

DAVID M. RAPOPORT, Appellant, v. WILLIAM C. DEMENT, MARK R. ROSEKIND, and JEFFREY L. SCHWIMMER, Appellees.

00-1451

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

254 F.3d 1053; 2001 U.S. App. LEXIS 14322; 59 U.S.P.Q.2D (BNA) 1215

June 28, 2001, Decided

**PRIOR HISTORY:** [\*\*1] Appealed from: U.S. Patent and Trademark Office Board of Patent Appeals and Interferences. (Interference No. 102,760).

**DISPOSITION:** AFFIRMED.

**CASE SUMMARY:**

**PROCEDURAL POSTURE:** Appellant challenged a final decision of the Board of Patent Appeals and Interferences which awarded judgment of priority as to the sole count of the interference in favor of appellees and made other rulings in favor of appellees.

**OVERVIEW:** The count in this interference related to the treatment of sleep apnea by administering a therapeutically effective amount of certain azapirone compounds such as buspirone. Before the court, appellant did not contest either the ultimate priority determination in favor of appellees or the board's underlying findings. Instead, he argued that the board erred in not finding that all of appellees' claims corresponding to the count were either anticipated by appellant's published prior art reference or rendered obvious by the publication in combination with admissions allegedly made in appellees' '325 application. He also argued that it was an abuse of discretion for the board to deny his Motion to Accept Belated Filing and to dismiss his Belated Motion for Judgment as untimely. The court first concluded that the board was correct in its interpretation of "treatment of sleep apneas." The court next rejected the merits of appellant's anticipation argument. The board's conclusion was supported by substantial evidence. The board did not abuse its discretion by denying appellant's Motion to Accept Belated Filing or in dismissing the preliminary motion for judgment.

**OUTCOME:** The decision was affirmed.

LexisNexis(R) Headnotes

*Patent Law > Nonobviousness > Evidence & Procedure > Fact & Law Issues*

*Patent Law > Anticipation & Novelty > Elements*

*Patent Law > Anticipation & Novelty > Fact & Law Issues*

[HN1] To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. Anticipation is a question of fact, and the court upholds decisions of the Board of Patent Appeals and Interferences on factual matters if there is substantial evidence in the record to support the board's findings. Whether a claim limitation is inherent in a prior art reference is a factual issue on which evidence may be introduced. The board's determination of obviousness is a question of law subject to de novo review. However, the board's factual determinations underlying its rulings on anticipation and obviousness are reviewed under the substantial evidence test. Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

*Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview*

*Patent Law > Jurisdiction & Review > Standards of Review > General Overview*

[HN2] The Board of Patent Appeals and Interferences' decisions to deny a Motion to Accept Belated Filing and to dismiss a Belated Motion for Judgment are reviewed for abuse of discretion. An abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact finding; or (4) involves a record that contains no evidence on which the board could rationally base its decision.

***Patent Law > Date of Invention & Priority > Reduction to Practice******Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > Patentability & Priority Determinations******Patent Law > Jurisdiction & Review > Standards of Review > General Overview***

[HN3] The Board of Patent Appeals and Interferences' legal conclusions regarding priority, conception, and reduction to practice are reviewed de novo.

***Patent Law > Infringement Actions > General Overview******Patent Law > Anticipation & Novelty > General Overview***

[HN4] Only when a claim is properly understood can a determination be made whether the claim "reads on" an accused device or method, or whether the prior art anticipates and/or renders obvious the claimed invention.

***Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview******Patent Law > Anticipation & Novelty > General Overview***

[HN5] The court reviews the Board of Patent Appeals and Interferences' legal conclusion, as it does all rulings on claim interpretation, without deference.

***Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > General Overview***

[HN6] Interference counts are given the broadest reasonable interpretation possible, and resort to the specification is necessary only when there are ambiguities inherent in the claim language or obvious from arguments of counsel.

***Patent Law > Anticipation & Novelty > Description in Publications******Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > General Overview******Patent Law > Jurisdiction & Review > Standards of Review > General Overview***

[HN7] What a reference teaches is a question of fact. Therefore, the court reviews the Board of Patent Appeals and Interferences' characterization of the disclosure in a publication for substantial evidence.

***Patent Law > Anticipation & Novelty > General Overview***

[HN8] A reference anticipates a claim if it discloses the claimed invention such that a skilled artisan could take the teachings of the reference in combination with his own knowledge of the particular art and be in possession of the invention.

***Patent Law > Anticipation & Novelty > General Overview***

[HN9] Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

***Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview***

[HN10] Copending applications invoke the preponderance of the evidence standard.

***Patent Law > Anticipation & Novelty > Accidental Anticipation & Inherency******Patent Law > Anticipation & Novelty > Fact & Law Issues******Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview***

[HN11] The issue of anticipation -- whether by inherency or otherwise -- is a question of fact, and the court upholds decisions of the Board of Patent Appeals and Interferences on factual matters if there is substantial evidence in the record to support the board's findings.

**COUNSEL:** Roger L. Browdy, Browdy and Neimark, P.L.L.C, of Washington, DC, argued for appellant.

David S. Abrams, Roylance, Abrams, Berdo & Goodman, L.L.P., of Washington, DC, argued for appellee. With him on the brief was Robert H. Berdo.

**JUDGES:** Before CLEVINGER, RADER and GAJARSA, Circuit Judges.

**OPINIONBY:** CLEVINGER

**OPINION:** [\*1055]

CLEVINGER, Circuit Judge.

David M. Rapoport ("Rapoport") appeals from a final decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office ("Board") dated February 29, 2000. The real parties in interest in this interference are: (1) New York University ("NYU"), assignee of Rapoport; (2) the Board of Trustees of the Leland Stanford Junior University ("Stanford"), assignee of William C. Dement ("Dement") and

Mark R. Rosekind ("Rosekind"); and (3) the Bristol-Myers Squibb Company ("Bristol-Myers"), assignee of Jeffrey L. Schwimmer ("Schwimmer"). Collectively, Dement, Rosekind, and Schwimmer will be referred to herein as "Dement et al. "

The Board awarded judgment of priority as to the [\*\*2] sole count of the interference in favor of Dement et al., and further ordered that Dement et al. are entitled to a patent containing claims 1-13 of U.S. Patent Application No. 07/695,325 ("the '325 application"), filed May 3, 1991, and that Rapoport is not entitled to a patent containing claims 1-12 of U.S. Patent Application No. 07/479,693 ("the '693 application"), filed February 14, 1990. We affirm.

# I

The subject matter at issue in this case is a method for the treatment of sleep apnea. Generally, sleep apnea refers to the transient cessation of breathing during sleep. As described by the Board:

Sleep apneas comprise a spectrum of disorders with varying severity and morbidity and are usually classified as being an obstructive, central, or mixed apnea, depending on the presence or absence of respiratory efforts during the periods in which airflow has ceased. Obstructive and mixed apneas occur with greatest frequency with the most familiar being obstructive sleep apnea syndrome in which sporadic recurring collapse of the patient's upper airway occurs during sleep. If the collapse is complete, there is no air exchange at the nose and mouth and breathing is interrupted. [\*\*3] The usual result is a partial arousal and a return to normal breathing.

In most instances, patients suffering from sleep apnea have no knowledge or memory of the apnea episodes, but find themselves constantly suffering from fatigue and daytime drowsiness for no apparent reason. Consequently, due to this chronic lack of proper rest, patients who suffer from sleep apnea often exhibit secondary symptoms of anxiety, depression, fatigue, malaise, irritability, anger, hostility, and other similar problems.

The count in this interference relates to the treatment of sleep apnea by administering a therapeutically effective amount of certain azapirone compounds such as buspirone "to a patient in need of such treatment."

On February 12, 1990, Schwimmer filed U.S. Patent Application No. 07/478,820 ("the '820 application"). Claim 1 of the '820 application as originally filed reads in relevant part:

1. A method for treatment of sleep apneas comprising administration of a therapeutically effective regimen of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . . .

There is no dispute that although [\*\*4] buspirone is an azapirone compound, the azapirone compounds of Schwimmer's Formula I exclude buspirone. On the same day, Dement, Rosekind, and Schwimmer jointly filed U.S. Patent Application No. 07/479,803 [\*1056] ("the '803 application"). Original claim 1 of the '803 application reads as follows in its entirety:

1. A method for treatment of sleep apneas comprising administration of a therapeutically effective regimen of buspirone or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment.

Two days later, on February 14, 1990, Rapoport filed the '693 application. Claim 1 of the '693 application reads as follows in relevant part:

1. A method for treatment of sleep apneas comprising administration of a therapeutically effective regimen of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . . .

The azapirone compounds of Rapoport's Formula I include buspirone, and claim 6 of Rapoport's '693 application is specifically directed to buspirone.

On February 12, 1991, Schwimmer filed U.S. Patent Application No. 07/657,332 ("the '332 application") [\*\*5] as a continuation of the '820 application, and on May 3, 1991, Dement, Rosekind, and Schwimmer jointly filed the '325 application as a continuation-in-part of the '803 and '332 applications. Original claim 1 of the '325 application reads as follows in relevant part:

1. A method for treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition salt thereof to a patient in need of such treatment . . . .

The azapirone compounds of Formula I in the context of the '325 application include buspirone, and claim 7 of the '325 application is specifically directed to buspirone.

On January 10, 1992, an interference was declared, and Dement et al. were accorded the benefit of the February 12, 1990, filing date of the '820 and '803 parent applications and therefore designated as the senior party. Count 1 of the interference, the only count at issue, reads in pertinent part as follows:

A method for treatment of sleep apneas comprising administration of a therapeutically effective amount of a Formula I azapirone compound or a pharmaceutically effective acid addition [\*\*6] salt thereof to a patient in need of such treatment . . . .

The azapirone compounds of Formula I in the context of the interference count include buspirone. Claims 1-12 of Rapoport's '693 application and claims 1-13 of the Dement et al. '325 application correspond to the count.

On June 10, 1992, Rapoport filed a Motion for Judgment pursuant to 37 C.F.R. § 1.633(a) in which he argued, inter alia, that the subject matter of the count was not patentable to Dement et al., on the grounds that it was anticipated and/or rendered obvious pursuant to 35 U.S.C. § 102(a) and/or 35 U.S.C. § 103 by a prior art reference authored by Rapoport. This reference, entitled "Buspirone: Anxiolytic Therapy with Respiratory Implications," was published in Family Practice Recertification in September 1989, at pages 32-37 of Vol. 11, No. 9 (Supplement) ("the FPR Publication"). We note that the FPR Publication does not constitute a statutory bar against either Dement et al. or Rapoport, since it was published less than one year before the priority filing date of the '325 and '693 applications. 35 U.S.C. § § 102 [\*\*7] (a) and 102(b) (1994). However, because the FPR Publication was authored by Rapoport, it can be cited as prior art against Dement et al., but not against Rapoport. 35 U.S.C. § 102 (1994); *In re Katz*, 687 [\*1057] F.2d 450, 454, 215 U.S.P.Q. (BNA) 14, 17 (CCPA 1982). Dement et al. do not contest the fact that the FPR Publication is a prior art reference that may be cited against them in this interference.

On October 29, 1992, pursuant to 37 C.F.R. § 1.602(b), Dement and Rosekind disclosed that they were obligated to assign their rights in the '325 application to Stanford, and Schwimmer disclosed that he was obligated to assign his rights to Bristol-Myers. Approximately eight months later, on June 21, 1993, Dement et al. explicitly stated on the record that Schwimmer was the sole inventor of the use of most of the azapirone compounds covered by the count except for buspirone in the treatment of sleep apnea. On July 9, 1993, Rapoport filed a Second Motion to Accept Belated Filing Of Preliminary Motion Under 37 C.F.R. § 1.633(a) ("Rapoport's Motion to Accept Belated Filing"), along with a Motion for Judgment [\*\*8] Under C.F.R. § 1.633(a) ("Rapoport's Belated Motion for Judgment") arguing that claims in the Dement et al. '325 application are unpatentable under 35 U.S.C. § 102(g) and/or § 103 over the prior invention of claims 7 and 13 of Dr. Dement, which were invented by a different inventive entity.

On April 12, 1996, the Board rendered a decision which, inter alia, denied Rapoport's June 10, 1992, Motion for Judgment, denied Rapoport's Motion To Accept Belated Filing, and dismissed Rapoport's Belated Motion for Judgment as being untimely. These decisions were adhered to in a decision for reconsideration dated September 6, 1996. The Board rendered its final decision on February 29, 2000.

In its decision dated April 12, 1996, the Board found that: (1) Rapoport had established a conception date of May 13, 1988; (2) Dement was entitled to a 1986 date of conception; and (3) the conception by Dement inures to the benefit of Dement et al. pursuant to 35 U.S.C. § 116. Based on these findings, the Board awarded priority of the invention of the interference count to Dement et al. Before this court, Rapoport does not contest either the [\*\*9] ultimate priority determination in favor of Dement et al. or the underlying findings by the Board.

Instead, on appeal, Rapoport argues that the Board erred in not finding that all of the Dement et al. claims corresponding to the count are either anticipated by the FPR Publication or rendered obvious by the FPR Publication in combination with admissions allegedly made in the Dement et al. '325 application. Rapoport also argues that it was an abuse of discretion for the Board to deny Rapoport's Motion to Accept Belated Filing and to dismiss Rapoport's Belated Motion for Judgment as being untimely. Finally, Rapoport argues that--in the event that this court finds that all of the Dement et al. claims are unpatentable in view of the FPR Publication--the Board erred in awarding judgment on priority in favor of Dement et al. We have jurisdiction to hear this appeal pursuant to 28 U.S.C. § 1295(a)(4)(A) (1994) and 35 U.S.C. § 141 (1994).



## II

[HN1] To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q.2D (BNA) 1429, 1431 (Fed. Cir. 1997). [\*\*10] Anticipation is a question of fact, and we uphold decisions of the Board on factual matters if there is substantial evidence in the record to support the Board's findings. *In re Hyatt*, 211 F.3d 1367, 1371-72, 54 U.S.P.Q.2D (BNA) 1664, 1667 (Fed. Cir. 2000). Whether a claim limitation is inherent in a prior art reference is a factual issue on which evidence may be introduced. *In re Schreiber*, 128 F.3d at [\*\*1058] 1477, 44 U.S.P.Q.2D (BNA) at 1431. The Board's determination of obviousness is a question of law subject to de novo review. However, the Board's factual determinations underlying its rulings on anticipation and obviousness are reviewed under the substantial evidence test. *Dickinson v. Zurko*, 527 U.S. 150, 50 U.S.P.Q.2D (BNA) 1930, 144 L. Ed. 2d 143, 119 S. Ct. 1816 (1999); *In re Gartside*, 203 F.3d 1305, 1316, 53 U.S.P.Q.2D (BNA) 1769, 1775-76 (Fed. Cir. 2000). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *In re Gartside*, 203 F.3d at 1312, 53 U.S.P.Q.2D (BNA) at 1773 (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229, 83 L. Ed. 126, 59 S. Ct. 206 (1938)). [\*\*11]

[HN2] The Board's decisions to deny Rapoport's Motion to Accept Belated Filing and to dismiss Rapoport's Belated Motion for Judgment are reviewed for abuse of discretion. *Abrutyn v. Giovanniello*, 15 F.3d 1048, 1050-51, 29 U.S.P.Q.2D (BNA) 1615, 1617 (Fed. Cir. 1994). An abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact finding; or (4) involves a record that contains no evidence on which the Board could rationally base its decision. Id.

As noted above, Rapoport has not requested review of the underlying factual determinations or of the legal bases for the Board's award of priority to Dement et al. Instead, Rapoport merely questions the Board's action of awarding priority to Dement et al. at the same time as holding the Dement et al. claims patentable. This issue involves [HN3] the Board's legal conclusions regarding priority, conception, and reduction to practice, which we review de novo. *Eaton v. Evans*, 204 F.3d 1094, 1097, 53 U.S.P.Q.2D (BNA) 1696, 1698 (Fed. Cir. 2000).

## III

We first address Rapoport's argument that the Dement [\*\*12] et al. claims corresponding to the count are anticipated by the FPR Publication. Because the first step of a patentability or invalidity analysis based on antici-

tion and/or obviousness in view of prior art references is no different from that of an infringement analysis, we must start by interpreting any disputed terms in the interference count. *Amazon.com, Inc. v. Barnesandnoble.com, inc.*, 239 F.3d 1343, 1351, 57 U.S.P.Q.2D (BNA) 1747, 1751-52 (Fed. Cir. 2001). [HN4] Only when a claim is properly understood can a determination be made whether the claim "reads on" an accused device or method, or whether the prior art anticipates and/or renders obvious the claimed invention. Id.

## A

Rapoport argues on appeal, as he did before the Board, that it is reasonable to interpret the phrase "method for treatment of sleep apneas" in the interference count broadly to include both (1) treatment of anxiety secondary to sleep apnea and (2) treatment of the underlying sleep disorder itself. In contrast, Dement et al. agree with the Board, which found that in the context of the present interference, treatment of the underlying sleep apnea disorder itself is distinct from treatment of [\*\*13] anxiety and other secondary symptoms related to sleep apnea. Based on this finding, the Board interpreted the term "treatment of sleep apneas" in the interference count as being limited to treatment of the underlying sleep apnea disorder itself. [HN5] We review the Board's legal conclusion, as we do all rulings on claim interpretation, without deference. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456, 46 U.S.P.Q.2D (BNA) 1169, 1174-75 (Fed. Cir. 1998) (en banc); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 U.S.P.Q.2D (BNA) [\*\*1059] 1321, 1329 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370, 38 U.S.P.Q.2D (BNA) 1461, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). Upon reviewing the record, we discern no error with the Board's interpretation.

First, we note that the disputed phrase "treatment of sleep apneas" is technically part of the preamble of the interference count, because it appears before the transition word "comprising." However, there is no dispute in this case that the phrase should be treated as a claim limitation. Moreover, without treating the phrase "treatment of sleep apneas" as a claim limitation, the phrase "to a patient in need of such treatment" [\*\*14] would not have a proper antecedent basis.

In support of his proposed broad interpretation for "treatment of sleep apneas," Rapoport relies on the following passage from the written description of the Dement et al. '325 application:

There are two aspects to the use of azapirones in treating sleep apneas. The first is that the administration of an azapirone ef-

fectively reduces the frequency and severity of the apnea episodes during sleep. This is reflected in significantly increased undisturbed sleep and a significant increase in blood oxygen levels. The second aspect involves azapirone alleviation of the symptomatology associated with the occurrence of sleep apneas. The azapirone treatment alleviates the sleep apnea-related symptoms of anxiety, depression, fatigue, malaise, irritability, anger and hostility.

According to Rapoport, this passage supports the notion that "treatment of sleep apneas" in the interference count should include both treatment of the underlying disorder and the "symptomatology associated with the occurrence of sleep apneas." However, to the extent that the above passage suggests that "alleviation of the symptomatology associated with the [\*\*15] occurrence of sleep apneas" constitutes an aspect of the use of azapirones in treating sleep apneas, the intrinsic record in this case leads to the conclusion that "treatment of sleep apneas" refers only to treatment of the underlying sleep apnea disorder.

First, the plain language of the interference count unambiguously refers to "treatment of sleep apneas" narrowly defined, and does not also include by its plain terms "treatment of symptoms associated with sleep apneas." See *Davis v. Loesch*, 998 F.2d 963, 968, 27 U.S.P.Q.2D (BNA) 1440, 1444 (Fed. Cir. 1993) ("[HN6] Interference counts are given the broadest reasonable interpretation possible, and resort to the specification is necessary only when there are ambiguities inherent in the claim language or obvious from arguments of counsel.") (citations omitted); *In re Hyatt*, 211 F.3d at 1372, 54 U.S.P.Q.2D (BNA) at 1667 (during examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification). Here, Rapoport relies on the written description of the Dement et al. '325 application in an unsuccessful attempt to broaden the phrase "treatment of sleep apneas" from its ordinary [\*\*16] meaning, which narrowly refers to treatment of the underlying disorder itself.

Contrary to Rapoport's assertions, the written description of the Dement et al. '325 application actually confirms the Board's interpretation, and explicitly defines "sleep apneas":

In the context of this invention, sleep apneas comprise all the sub-categories such as those caused by upper airway obstruction; those whose origins arise in the cen-

tral nervous system; and those of a mixed type with contribution from both components.

This passage indicates that the term "treatment of sleep apneas" refers to reducing [\*1060] or eliminating sleep apneas caused by upper airway obstructions, sleep apneas whose origins arise in the central nervous system, and sleep apneas of a mixed type.

As further support for the Board's position, the Summary of the Invention in the Dement et al. '325 application states that "for use in the instant method oral administration of a dose of from about 10 to 60 mg of an azapirone at the hour of sleep is usually employed." This description is consistent with treatment of the underlying sleep apnea disorder, which by definition manifests itself during sleep, and inconsistent [\*\*17] with treatment of anxiety and other symptoms commonly associated with sleep apnea, which would obviously manifest themselves while a patient is awake.

Next, in a portion of the Detailed Description of the Invention not limited to any particular embodiment, the Dement et al. '325 application states as follows:

The present invention concerns a method for treating sleep apneas comprising obstructive, central and mixed apneas, in a patient population that ranges from infants to geriatric-aged individuals.

Once again, this passage defines sleep apneas in terms of the underlying respiratory disorder and uses the term "treating sleep apneas" in a manner that is consistent with the Board's interpretation.

Finally, when describing the effectiveness of the sleep apnea treatment method that is disclosed and claimed in the Dement et al. '325 application, the discussion is limited to the treatment's effect on the underlying sleep apnea disorder, and does not mention the treatment's effect on the associated symptomatology:

The effectiveness of azapirone treatment of patients suffering from sleep apneas can be exemplified by clinical experience with buspirone. Single [\*\*18] dose administration of buspirone, given at bedtime to patients suffering from obstructive sleep apnea, resulted in increased sleep efficiency with experimentally derived measurements showing a gain in total

sleep time and a marked reduction in episodes of sleep disturbance. One of the most consistent physiological measurements of improvement was a 10 to 20% increase in blood oxygen levels, an indication of improved respiratory efficiency.

In other words, Dement et al. noted that treating patients suffering from obstructive sleep apnea with buspirone at bedtime had a measurably beneficial effect on the underlying sleep apnea disorder (i.e., increased sleep efficiency, gain in total sleep time, significant reduction in episodes of sleep disturbance, and improved respiratory efficiency). However, Dement et al. made no mention in the written description of the '325 application of specific evidence of the treatment's effect on the symptomatology commonly associated with sleep apnea.

We therefore conclude that the Board was correct in interpreting "treatment of sleep apneas" as being limited to treatment of the underlying sleep apnea disorder, i.e., reducing the [\*\*19] frequency and severity of the apnea episodes during sleep.

#### B

Having construed the disputed term in the interference count and affirmed the Board's interpretation, we can properly address the merits of Rapoport's anticipation argument. The Board found that the disclosure of the FPR Publication was limited to treatment of anxiety in patients suffering from sleep apnea with buspirone, and did not address treatment of the underlying sleep apnea disorder. [HN7] What a reference teaches is a question of fact. *In re Beattie*, 974 F.2d 1309, 1311, 24 U.S.P.Q.2D (BNA) 1040, 1041-42 (Fed. Cir. 1992). [\*1061] Therefore, we review the Board's characterization of the disclosure in the FPR Publication for substantial evidence. *In re Gartside*, 203 F.3d at 1316, 53 U.S.P.Q.2D (BNA) at 1775-76. The record indicates that substantial evidence supports the Board's factual findings regarding the FPR Publication.

There is no disclosure in the FPR Publication of tests in which buspirone is administered to patients suffering from sleep apnea with the intent to cure the underlying condition. As the Board correctly found, the FPR Publication focuses on the treatment of anxiety with buspirone, and indicates [\*\*20] that buspirone has potential as a primary treatment for dyspnea (which simply refers to difficulty in breathing in general).

For example, a passage in the FPR Publication mentions the possibility of administering buspirone to patents suffering from sleep apnea, but this is for the purpose of treating anxiety in such patients, not for the purpose of treating the sleep apnea disorder itself:

Buspirone thus appears to be an anxiolytic agent with a profile of respiratory effects that make it potentially safer to use for patients with impaired respiratory function and for patients with diseases such as obstructive sleep apnea, when use of ventilatory depressants would be clearly dangerous.

Rapoport concedes as much:

While this passage does not disclose administering buspirone with the intent of treating the sleep apnea per se, such an explicit intent is not necessary in order to anticipate the claims of Dement corresponding to the count.

Rapoport Opening Brief before the Board filed July 5, 1994. In a nutshell, using Rapoport's own words from its Opening Brief before the Board, Rapoport's theory on anticipation is as follows:

As long as one [\*\*21] administers buspirone to a patient with sleep apnea in a therapeutically effective amount, at least claims 1, 2, 6 and 7 of the Dement et al [sic] application underlying the present proceeding are fully anticipated.

In other words, according to Rapoport, neither the reasons for administering buspirone to the patient nor the time of administration are relevant. Instead, according to Rapoport, the only requirement of the count is that the patient suffer from sleep apnea. Given our disagreement with Rapoport's proposed claim interpretation, this argument cannot succeed.

Moreover, the need for tests to confirm safety for treating anxiety in patients with sleep apnea is indicated in the very next sentence of the FPR Publication relating to treating patients suffering from anxiety: "The preliminary results found among healthy subjects need to be confirmed by directly testing patients who need anxiolytic therapy." Thus, even the proposed testing in the FPR Publication is limited to the treatment of patients suffering from anxiety, not from sleep apnea. Moreover, the lack of information concerning administration of buspirone to patients while sleeping is indicated in Table

3 [\*\*22] of the FPR Publication, where the entry under "Buspirone" regarding its effect on upper airway tone during sleep is "Undetermined."

The Board also correctly found that the FPR Publication does not show administering buspirone in any specific amounts to patients suffering from sleep apnea. Rather, the FPR Publication discloses administering single oral doses of 10 mg to nine normal volunteers. It also discloses administering buspirone in an amount of 10 mg three times a day to two patients with "severe alveolar hypoventilation" who needed anxiolytic therapy to facilitate use of a nocturnal ventilator. There is no [\*1062] dispute that none of these patients are reported as suffering from sleep apnea in the FPR Publication.

In contrast, as mentioned earlier, the Dement et al. '325 application discloses that based on clinical experience, administration of a single dose of buspirone at bedtime to patients suffering from obstructive sleep apnea resulted in a marked reduction in episodes of sleep disturbance, and further discloses administration of 20-40 mg of buspirone at the hour of sleep to an average adult.

We note that there is no mention in the FRP Publication of administering buspirone [\*\*23] to a patient at bedtime. The significance of this fact, of course, is that sleep apnea, by definition, occurs during sleep. In one of the two tests mentioned in the FPR Publication, a single 10 mg dosage was given at an unspecified time, while in the second test buspirone was administered in doses of 10 mg three times a day, once again without specifying administering the buspirone at bedtime.

Finally, we note that Rapoport argues that the FPR Publication inherently anticipates the count even under the Board's claim interpretation. See *In re Graves*, 69 F.3d 1147, 1152, 36 U.S.P.Q.2D (BNA) 1697, 1701 (Fed. Cir. 1995) (noting that [HN8] a reference anticipates a claim if it discloses the claimed invention such that a skilled artisan could take the teachings of the reference in combination with his own knowledge of the particular art and be in possession of the invention) (citations omitted). According to Rapoport:

The anxiolytic amount of buspirone taught by the FPR publication still inherently anticipates in view of the fact that the Dement et al. application contains disclosures that anxiolytic amounts of buspirone overlap the preferred therapeutically effective amounts [\*\*24] of buspirone disclosed in the Dement et al. application for reducing the frequency and severity of the apnea episodes during sleep.

Specifically, Rapoport bases his argument on the observation that the Dement et al. application specifies administration of buspirone at the hour of sleep in dosages of about 20-40 mg for an average adult. Next, Rapoport notes that the FPR Publication discloses a dosage of 10 mg of buspirone three times a day for treatment of anxiety. The conclusion to be drawn from these observations, according to Rapoport, is as follows:

The fact that the Dement et al. specification recites a preferred range of 20-40 mg of buspirone administered at the time of sleep does not suggest that the administration of 10 mg of buspirone at the time of sleep, particularly when there have been two other dosages of 10 mg each during the course of the day, will have no therapeutic effect. The claims do not require optimal amounts, only therapeutically effective amounts. If 10 mg of buspirone has any effect on the treatment of sleep apnea, even if not optimum, the claim is anticipated.

We conclude that Rapoport's inherency argument is without merit. First, [\*\*25] Rapoport neglects to point out that the FPR Publication explicitly states that the patients who received the 10 mg doses of buspirone three times a day were suffering from "severe alveolar hypoventilation who needed anxiolytic therapy to facilitate the use of a nocturnal ventilator," not from sleep apnea. Second, Rapoport's argument is based on at least two speculative assumptions: (1) that a treatment regimen of three doses a day would necessarily include an administration "at the time of sleep;" and (2) that administering two 10 mg doses of buspirone at unspecified times throughout the day in conjunction with a 10 mg dose of buspirone at bedtime would [\*1063] necessarily result in a "therapeutically effective amount" of buspirone treatment for the purpose of treating the underlying sleep apnea disorder. "[HN9] Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 U.S.P.Q.2D (BNA) 1746, 1749 (Fed. Cir. 1991) (emphasis in original) (citations omitted). Rapoport has not attempted to demonstrate that [\*\*26] the proposed dosage regimen in the FPR Publication would necessarily result in a therapeutically effective amount. Instead, Rapoport merely argues that the "preferred" range of 20-40 mg described in the Dement et al. application does not rule out the thrice-daily 10 mg doses of buspirone discussed in the FPR Publication in the context of patients who are

not even described as suffering from sleep apnea. The burden of proof, of course, is on Rapoport, by a preponderance of the evidence. *Bruning v. Hirose*, 161 F.3d 681, 685-86, 48 U.S.P.Q.2D (BNA) 1934, 1937-38 (Fed. Cir. 1998) ([HN10] copending applications invoke the preponderance of the evidence standard).

Most importantly, however, as we noted at the outset, [HN11] the issue of anticipation--whether by inherency or otherwise--is a question of fact, and we uphold decisions of the Board on factual matters if there is substantial evidence in the record to support the Board's findings. *In re Hyatt*, 211 F.3d at 1371-72, 54 U.S.P.Q.2D (BNA) at 1667. In this case, as detailed above, our review of the record indicates that the Board's findings are amply supported by the evidence. The Board considered the evidence of record and correctly [\*\*27] ruled against Rapoport on this issue.

Therefore, for all the reasons stated above, we find that the Board's conclusion that the FPR Publication does not disclose administration of buspirone to patients suffering from sleep apnea to treat sleep apnea is supported by substantial evidence.

#### IV

Next, we address Rapoport's argument that the Board's action of denying Rapoport's Motion to Accept Belated Filing was an abuse of discretion. As noted earlier, this motion alleged that the Dement et al. claims are either anticipated under 35 U.S.C. § 102(g) and/or rendered obvious under 35 U.S.C. § 102(g) and/or § 103 over the prior invention of claims 7 and 13 of Dr. Dement, which were invented by a different inventive entity.

Our review of the record indicates that the Board denied the Motion to Accept Belated Filing on the basis that Rapoport had filed it on July 9, 1993, approximately eight months after Rapoport should have been aware of the facts upon which the motion was based. As the Board correctly noted, Rapoport should have been aware when

the interference was declared that the notice of interference accorded Dement et al. the [\*\*28] benefit of the abandoned '820 application, wherein Dr. Schwimmer signed an oath stating that he is the sole inventor of the claimed subject matter (i.e., using azapirones other than buspirone to treat sleep apnea). Moreover, the Board correctly indicated that Rapoport learned or should have been aware of the grounds of unpatentability urged in the preliminary motion for judgment on or about October 29, 1992, when Dement et al. filed a notification pursuant to 37 C.F.R. § 1.602(b) stating that Drs. Dement and Rosekind were obligated to assign their entire interest to Stanford and that Dr. Schwimmer was obligated to assign his entire interest to Bristol-Myers.

In view of the above, we conclude that the Board did not abuse its discretion by denying Rapoport's Motion to Accept Belated [\*\*1064] Filing or in dismissing the preliminary motion for judgment, because there is evidence of record upon which the Board could base its decision that Rapoport did not show "sufficient cause" why the motion was not filed sooner, as required by 37 C.F.R. § 1.645(b).

#### V

Finally, we turn to Rapoport's argument that the Board erred in awarding judgment [\*\*29] on priority in favor of Dement et al. against Rapoport, notwithstanding the possibility that all of the Dement et al. claims could be ruled unpatentable to Dement et al. As Rapoport acknowledges, we need not reach this issue, given our conclusion that the Board did not err in finding that the Dement et al. claims were not rendered unpatentable by the FPR Publication.

#### VI

For the reasons set forth above, the decision of the Board is, in all respects,

**AFFIRMED.**

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